

## **REMARKS**

The Office Action mailed November 14, 2007, has been received and carefully considered. The Specification has been amended in view of the formal objections thereof by submitting a Substitute Specification and the required Annotated Specification showing the changes made. Also included are editorial changes to correct errors in grammar, spelling and idiomatic expression. Claims 1, 2, 13-15, and 33-35 have been amended for formal reasons in accordance with U.S. Patent practice. "Use" claims 13-15 and 33-35 have been reworded as "process-of-use" in accordance with U.S. Patent practice in order to overcome the rejections thereof. New claims 36-51 have been added. Withdrawn non-elected claims 3-12 and 16-33 have been cancelled without disclaimer of the subject matter thereof and without prejudice to the filing of a Divisional Application directed thereto. To the best of the undersigned attorney's information and belief, these changes to the specification and claims contain no new matter.

**Claims 1, 2, 13-15, and 33-51 are active in the Application and are submitted to be in allowable condition for reasons given in the following.**

### **Specification and Claim Changes and Support**

In the Specification, the punctuation on page 6, line 13 has been corrected; the Tables on pages 7-11 have been aligned; and the boxes in Table 5 on page 22 have been corrected to be "I", "II", "III", and "IV".

Claims 1 and 2 have been amended for formal reasons in accordance with U.S. Patent practice.

"Use" claims 13-15 and 33-35 have been reworded as "process-of-use" in accordance with U.S. Patent practice in order to overcome the rejections thereof. New claims 36-51 have been added.

New claims 36-51 find support in claims 1, 2, 13-15 and 33-35.

**I. The objection to the Specification is submitted overcome by the amendments made in the Substitute Specification submitted herewith.**

**II. The rejection of claims 13-15 and 33-35 under 35 USC §101 is submitted overcome by the amendments made herein these claims.**

**III. The rejection of claims 13-15 and 33-35 under 35 USC §112 is submitted overcome by the amendments made herein to these claims.**

**IV. The rejection of claims 1, 2, 13-15, and 33-35 under 35 U.S.C. §103(a) as unpatentably obvious over *Hu* (CN 1,168,278 A) is respectfully traversed.**

The Examiner considers that *Hu* discloses a traditional Chinese medicine comprising six active constituents in combination: semen momordicae, hydnocarpus seed, pangolin scales, rhubarb, licorice and bamboo shavings, that have a curative effect on gastric cancer and liver cancer, and the like. The Examiner acknowledges that the disclosure of *Hu* does not teach Applicant's claimed amounts of constituents.

The Examiner therefore has taken the position that, "The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. ", and cites *In re Aller*.

*Hu* discloses a traditional Chinese medicine comprising six active constituents in combination: semen momordicae, hydnocarpus seed, pangolin scales, rhubarb, licorice and bamboo shavings. The composition of the present invention is distinguishable as achieving anti-tumor properties when comprised of only five active constituents and in the amounts recited: 1 part by weight of hydnocarpus; 0.8-1.4 parts by weight of cochinchina momordica seed; 0.5-1.1 parts by weight of pangolin scales; 0.8-1.3 parts by weight of rhubarb; and 1-1.5 parts by weight of licorice root. That is, the composition of the present invention does not contain bamboo shavings.

Applicant respectfully submits that the Examiner's position that the claimed amounts of constituents can be obtained by one of ordinary skill in this art by "routine optimization" is unreasonable on its face in view of the extremely large number of tests that would be needed. This is submitted to be the case (1) because the amount of each constituent has a relation to the remaining four constituents, (2) because there is no teaching or suggestion in *Hu* of eliminating one or more of the six active constituents used in combination therein, and (3) because testing the anti-cancer effect of each possible formulation in a matrix of ranges of amounts of five constituents would represent a huge investment of material and human resources. Thus, Applicant submits that there would be nothing "routine" about the scope of the effort needed in view of these two considerations.

Further, because there is no teaching or suggestion in *Hu* to eliminate one or more of the six active constituents used in combination therein, Applicant submits that one of ordinary skill in this art would be left with no guidance as to which constituent – of the six active constituents used in *Hu* in combination, could be helter-skelter eliminated in trials. This is particularly the case with respect to new claims 36-51 (see the preamble of independent claim 36 "consisting essentially of" and the preamble of claim 44 "consisting of"). In view of these points, Applicant submits that the disclosure of *Hu* does not teach or suggest Applicant's claimed composition.

Moreover, Applicant submits that one of ordinary skill in this art would not be led or motivated to eliminate one of the six active constituents used in combination in the composition of *Hu* with any reasonable expectation of continuing to have a therapeutically effective composition. Further, Applicant submits that one of ordinary skill in this art would not be led or motivated to tinker with the compositional amounts with any reasonable expectation of continuing to have a therapeutically effective composition. In view of these points, Applicant submits that the disclosure of *Hu* may not be fairly said to teach or suggest Applicant's claimed composition so that no *prima facie* case of obviousness has been made out and this ground of rejection should be withdrawn.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that claims 1, 2, 13-15, and 33-51, and the Application are in condition for allowance.


Reconsideration and passage of this case to issue are therefore requested.

Should the Examiner consider that a conference would help to expedite the prosecution of this Application, the Examiner is invited to contact the undersigned to arrange for such an interview.

**Request For Extension of Time**

Applicant requests a first extension of time for responding to the Office Action dated November 14, 2007. A first extension fee of \$120.00 is now due. This fee is submitted herewith in the attached credit card form PTO-2038. Should the remittance be accidentally missing or insufficient, the Commissioner is hereby authorized to charge the fee to our Deposit Account No. 18-0002 and is requested to advise us accordingly.

Respectfully submitted,



Steven M. Rabin (Reg. No. 29,102)  
Rabin and Berdo PC  
CUSTOMER NO. 23995  
1101 - 14th Street, N.W., Suite 500  
Washington, D.C. 20005  
Tel.: (202) 371-8976  
Fax: (202) 408-0924

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Date

SMR/AJW:ac